K090534

MAQUET

510(k) Summary

[as required by 21 CFR 807.92(c)]

Submitter	**MAQUET Cardiopulmonary AG** Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person	Frank Moehrke Phone: 011 49 7478 921 229 Fax: 011 49 7478 921 400
Date Prepared	February 25, 2009
Device Trade Name	**Venous Hardshell Cardiotomy Reservoirs with Softline Coating**
Common/Usual Name	Venous Hardshell Reservoir
Classification Names	Cardiopulmonary bypass blood reservoir *(21 CFR 870.4400 – Product Code: DTN)* Cardiopulmonary bypass defoamer *(21 CFR 870.4230 – Product Code: DTP)* Cardiopulmonary bypass cardiotomy suction line blood filter *(21 CFR 870.4270 – Product Code: JOD)*
Legally Marketed Devices	- Jostra Venous Hardshell Cardiotomy Reservoirs with Safeline Coating (K061743), - QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with Softline Coating (K082117)

DEC 23 2009

Device Description

The Venous Hardshell Cardiotomy Reservoir is a reservoir with integrated filters and a defoamer. It is designed to be open or vacuum-tight. It may be marketed both as single product and as pre-assembled combination with the QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with Softline Coating (K082117).

Indications for Use

The Venous Hardshell Cardiotomy Reservoir, non-vacuum-tight, is designed to collect, store and filter the blood in an extracorporeal circuit during cardopulmonary bypass procedures up to six hours in adult surgery. It can be integrated into almost all perfusion systems. The Venous Hardshell Cardiotomy Reservoir is designed and sold for use only as indicated.

The Venous Hardshell Cardiotomy Reservoir, vacuum-tight model, is designed to collect, store and filter the blood in an extracorporeal circuit during cardopulmonary bypass procedures with or without vacuum assisted venous return up to six hours in adult surgery. It can be integrated into almost all perfusion systems. The Venous Hardshell Cardiotomy Reservoir is designed and sold for use only as indicated. This reservoir is also designed to be used postoperatively as a drainage and autotransfusion reservoir (e.g. for chest drainage) to return autologous blood shed from the chest to the patient for volume replacement.

Statement of Technical Comparison

The Venous Hardshell Cardiotomy Reservoirs (vacuum-tight and non-vacuum-tight model) with Softline Coating are identical to the Jostra Venous Hardshell Cardiotomy Reservoirs with Safeline Coating with the only exception that the Venous Hardshell Cardiotomy Reservoirs with Softline Coating have been coated with Softline Coating instead of Safeline Coating. However, the Softline Coating is the same as with the QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with Softline Coating. Besides this difference the Venous Hardshell Cardiotomy Reservoirs with Softline Coating are the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as compared to the Venous Hardshell Cardiotomy Reservoirs with Safeline Coating.

Determination of Substantial Equivalence

Evaluation and testing on safety and effectiveness was executed to demonstrate that the Venous Hardshell Cardiotomy Reservoirs with Softline Coating described in this submission are substantially equivalent to the Jostra Venous Hardshell Cardiotomy Reservoirs with Safeline Coating as reservoirs and to the QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with Softline Coating regarding the Softline Coating and the pre-assembled combination of the reservoir with the oxygenator.

The following areas have been tested and / or evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the Venous Hardshell Cardiotomy Reservoirs (vacuum-tight and non-vacuum-tight model) with Softline Coating are substantially equivalent to the named predicate devices which hold currently market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Maquet Cardiopulmonary AG
c/o Mr. Frank Moehrke
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirringen
Germany

DEC 23 2009

Re: K090534
Maquet Venous Hardshell Cardiotomy Reservoirs with Softline Coating
Regulation Number: 21 CFR 870.4400
Regulation Name: Reservoir, Blood, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTN
Dated: November 23, 2009
Received: November 25, 2009

Dear Mr. Moehrke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090534

Device Name:

Venous Hardshell Cardiotomy Reservoirs with Softline Coating

Indications for Use:

The Venous Hardshell Cardiotomy Reservoir, non-vacuum-tight, is designed to collect, store and filter the blood in an extracorporeal circuit during cardopulmonary bypass procedures up to six hours in adult surgery. It can be integrated into almost all perfusion systems. The Venous Hardshell Cardiotomy Reservoir is designed and sold for use only as indicated.

The Venous Hardshell Cardiotomy Reservoir, vacuum-tight model, is designed to collect, store and filter the blood in an extracorporeal circuit during cardopulmonary bypass procedures with or without vacuum assisted venous return up to six hours in adult surgery. It can be integrated into almost all perfusion systems. The Venous Hardshell Cardiotomy Reservoir is designed and sold for use only as indicated. This reservoir is also designed to be used postoperatively as a drainage and autotransfusion reservoir (e.g. for chest drainage) to return autologous blood shed from the chest to the patient for volume replacement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090534

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